

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MICHAEL A. KAPIN, DAVID P. BINGAMAN,
DANIEL A. GAMACHE, GUSTAV GRAFF, and
JOHN M. YANNI

Appeal 2007-1075
Application 09/929,381
Technology Center 1600

Decided: June 28, 2007

Before, DONALD E. ADAMS, DEMETRA J. MILLS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

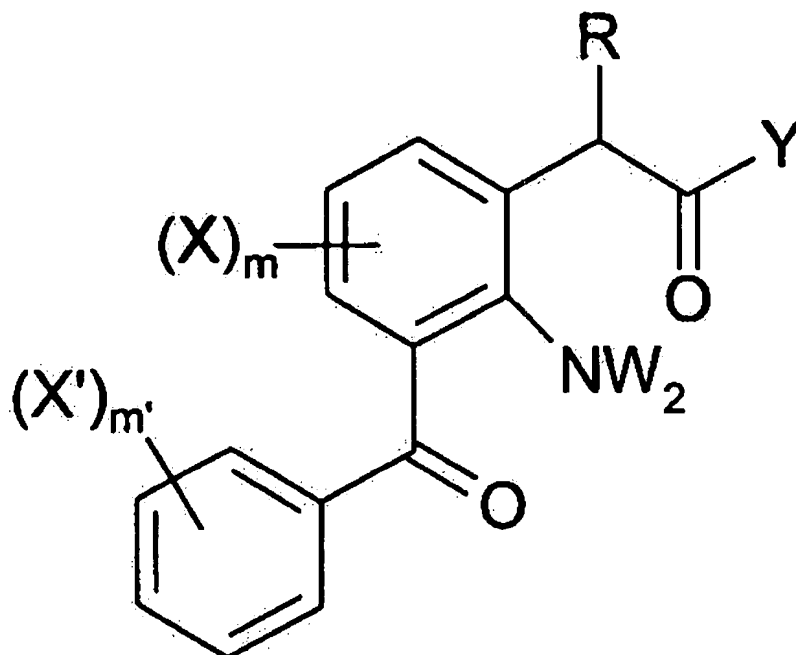
MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected claims 1-3 and 5-8.

Claim 1 is representative.

1. A method of treating an ophthalmic angiogenesis-related disorder in a patient suffering from such a disorder which comprises administering to the patient a therapeutically effective amount of 3-benzoylphenylacetic acid or a derivative thereof the formula:



wherein

R = H, C₁₋₄ (un)branched alkyl, CF₃, SR⁴,

Y = OR', NR''R';

R' = H, C₁₋₁₀ (un)branched alkyl, (un)substituted aryl (substitution as defined by X below),

(un)substituted heterocycle (substitution as defined by X below),

-(CH₂)_nZ(CH₂)_nA;

n = 2-6;

n' = 1-6;

Z = nothing, O, C=O, OC(=O), C(=O)O, C(=O)NR³, NR³C(=O), S(O)_n,
 CHOR³, NR³;

n² = 0-2;

R^3 = H, C_{1-6} (un)branched alkyl, (un)substituted aryl (substitution as defined by X below),
(un)substituted heterocycle (substitution as defined by X below);
A = H, OH, optionally (un)substituted aryl (substitution as defined by X below), (un)substituted heterocycle (substitution as defined by X below),
 $-(CH_2)_n, OR^3$;
 R'' = H, OH, OR' ;
X and X' independently = H, F, Cl, Br, I, OR' , CN, OH, $S(O)_n$, $2R^4$, CF_3 , R^4 , NO_2 ;
 R^4 = C_{1-6} (un)branched alkyl;
 m = 0-3;
 m' = 0-5; and
W = O, H.

Cited References

Bayly	US 5,994,379	Nov. 30, 1999
Kalgutkar	US 6,207,700 B1	Mar. 27, 2001
Hellberg	US 6,342,524 B1	Jan. 29, 2002

Grounds of Rejection

1. Claims 1-3 and 5-8 stand rejected under 35 U.S.C. § 103(a) for obviousness over Bayly or Kalgutkar in view of Hellberg.
2. Claims 1-3 and 5-8 stand rejected under 35 U.S.C. § 112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1-3 and 5-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 10-19 of copending 10/344,881.
4. Claims 1-3 and 5-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10 of copending 10/417,466.

We affirm rejections 1 and 2. Rejections 3 and 4 are mooted by abandonment of the copending applications.

DISCUSSION

1. Obviousness

Claims 1-3 and 5-8 stand rejected under 35 U.S.C. § 103(a) for obviousness over Bayly or Kalgutkar in view of Hellberg (Answer 3).

Appellants have not argued the claims separately. Therefore we select claim 1 as representative of the rejected claims. The Examiner contends that Bayly discloses that COX-2 inhibitors are useful to treat diabetic retinopathy and discloses the claimed routes of administration of COX-2 inhibitors. (Bayly, col. 9, ll. 17-19.) Kalgutkar discloses the COX-2 inhibitors are anti-angiogenic. (Kalgutkar, col. 1, ll. 16-26.) Hellberg teaches that a compound having the formula recited in claim 1 is a COX-2 inhibitor. (Hellberg, col. 5, line 56 to col. 7, line 10.)

The Examiner concludes

it would have been obvious to one of ordinary skill in the art to use the compounds of Kalgutkar in the method of Bayly to yield the instant method. That is because Kalgutkar discloses that . . . COX-2 inhibitors are antiangiogenic and Bayly discloses that COX-2 inhibitors are useful to treat angiogenic ophthalmic conditions like diabetic retinopathy. Additionally Hellberg discloses ophthalmic administration and the instant dosage of the instant COX-2 inhibitor.

(Answer 4.)

We agree that the Examiner has set forth a prima facie case of obviousness. Dorlands Medical Dictionary¹ defines diabetic retinopathy as

proliferative r. , proliferative diabetic r. diabetic retinopathy characterized by neovascularization of the retina and optic disk (which may project into the vitreous), proliferation of fibrous tissue, vitreous hemorrhage, and eventually retinal detachment with blindness.

Thus, diabetic retinopathy is an ophthalmic condition characterized by increased neovascularization and angiogenesis. Bayly teaches that COX-2 inhibitors treat diabetic retinopathy and Hellberg teaches that the claimed compound is a COX-2 inhibitor. Thus, one of ordinary skill in the art would have been motivated by Bayly to use other known COX-2 inhibitors to treat diabetic retinopathy, an “ophthalmic angiogenesis-related disorder” of claim 1.

Similarly, Kalgutkar teaches antiangiogenic and antitumorogenic COX-2 inhibitor compounds (Kalgutkar, col. 9, ll. 56-67), and Appellant's admit that the compound of the claimed invention differs from Kalgutkar compounds, in that it is a derivative the compounds disclosed in Kalgutkar. (Br. 6) Hellberg teaches that the claimed COX-2 inhibitors may be administered ophthalmically to treat ophthalmic disorders. (Hellberg, Col. 5, l. 6-66.) Thus, one of ordinary skill in the art, knowing from Kalgutkar that related COX-2 inhibitor compounds are antiangiogenic, would have been

¹ Available online at:

http://www.mercksource.com/pp/us/cns/cns_hl_dorlands.jspz.

motivated to administer the COX-2 inhibitor compound of Hellberg to the eye to treat angiogenic ophthalmic disorders.²

For the reasons discussed herein, we conclude that the combined teachings of the cited references support a prima facie case of obviousness of the claimed subject matter.

Appellants contend that Hellberg does not discuss treatment of angiogenesis-related disorders at all, but teaches administration of a combination of compounds (cyclooxygenase inhibitors and prostaglandins) to lower intraocular pressure. (Br. 7-9.) Appellants further argue that neither Bayly or Kalgutkar teach the claimed COX-2 inhibitors. (Br. 6.) At the same time, Appellants admit that the claimed compound is a "derivative of the compounds disclosed in Kalgutkar." (Br. 6.)

Non-obviousness, however, cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. *In re Merck & Co.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." *In re Gorman*, 933 F.2d 982, 986, 18 USPQ2d 1885,

² The compound of Hellberg, being a derivative of the compounds disclosed in Kalgutkar, would have been expected by one of ordinary skill in the art to exhibit and possess anti-angiogenic properties when administered.

1888 (Fed. Cir. 1991). In the present case it is Bayly – not Hellberg which Appellants attack - which describes the treatment of an angiogenesis-related disorder with COX-2 inhibitors. Moreover, Hellberg is relied upon the Examiner for its teaching of a COX-2 inhibitor that falls within the scope of claim 1. Thus, we do not find it persuasive that Hellberg teaches its compounds are for a different use; the motivation to have used Hellberg's compounds to treat an ophthalmic angiogenesis disorder is provided by Bayly.

Moreover, Appellants claim a new benefit (inhibition of angiogenesis) to an old process, i.e., the administration of COX-2 inhibitors to the eye to treat ophthalmic disorders. It is well recognized that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. *In re Woodruff*, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936 (Fed. Cir. 1990).

Where the prior art, as here, gives reason or motivation to make the claimed invention, the burden then falls on an Appellants to rebut that prima facie case. Such rebuttal or argument can consist of any other argument or presentation of evidence that is pertinent. *In re Dillon*, 919 F.2d 688, 692-93, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991).

We do not find that Appellants have presented sufficient argument or evidence to rebut the Examiner's prima facie case of obviousness. The rejection of claim 1 for obviousness is affirmed. Claims 2, 3, and 5-8 fall with claim 1.

2. Indefiniteness

Claims 1-3 and 5-8 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention.

The Examiner argues that the phrase "derivative thereof of the formula" in the claims is unclear as to whether the claims are limited to compounds having the recited formula. (Answer 3.)

Appellants attempt to make an amendment to claim 1 in the Claims Appendix attached to the Brief, but there is no indication on the record that the amendment has been entered.³ (Br. 11.)

We agree with the Examiner that the present claim wording is unclear as to whether the claims are limited to compounds having the recited formula. It would appear that Appellants recognized this and attempted to correct the error by Amendment. Because the record does not reflect the amendment has been entered, this rejection is affirmed.

3. Obvious-type double patenting

Claims 1-3 and 5-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 10-19 of copending Application Serial. No. 10/344,881. The patent office records indicate that this application was abandoned on November 28, 2006 for

³ The Examiner acknowledges the proposed Amendment set forth in the Brief, but does not comment on whether the Amendment has been entered. (Answer 2.) Since there is no indication in the Examiner's Answer or the Patent Office electronic records that the Amendment has been entered, we address claim 1 as if the Amendment attached to the Brief has not been entered.

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failure to respond to an office action. Therefore, this rejection has been rendered moot by abandonment of the cited application.

4. Claims 1-3 and 5-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10 of copending 10/417,466.

Appellants indicate that a terminal disclaimer will not be filed in this case because Ser. No. 10/417,466 has been abandoned. (Br. 10). We have confirmed in patent office records that Application Serial No. 10/417,466 was abandoned for failure to file a response to an office action. This rejection has been rendered moot.

SUMMARY

The obviousness and indefiniteness rejections are affirmed. The provisional obviousness-type double patenting rejections have been rendered moot by abandonment of these applications.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

dm

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